UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE PUBLIC DISCLOSURE BAR

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Rather than address the points Abbott made in its opening brief, Ven-A-Care devotes much of its response to extolling its own virtues as a *qui tam* relator in unrelated matters that are not before this Court. (*E.g.*, VAC Br. at 1-9.) Of course, those efforts (for which Ven-A-Care's principals already have been richly rewarded) have no bearing on the issue this Court must decide: namely, whether the allegations against Abbott *here* are based upon public disclosures for which Ven-A-Care is not the original source. The evidence allows no other conclusion.

Ven-A-Care alleges that Abbott violated the False Claims Act by (i) creating and maintaining a "false" AWP for four generic products – one antibiotic (vancomycin) and three solutions (saline, dextrose, and sterile water) – that was far higher than the true price healthcare providers actually paid; and (ii) marketing the "spread" between the inflated AWP and the true price in order to drive sales. Long before Ven-A-Care ever lodged its complaint, however, these issues were publicly disclosed. As but a few examples,

- In 1992, OIG published a study (undertaken at the HCFA's request) that specifically reported the existence of what plaintiffs now call "mega-spreads" on vancomycin – finding that, while the AWP for a 500 mL vial of vancomycin was $19.17, the actual price was $5.00 (a spread of 283%).
- From public sources, the head of CMS learned at least by 1993 that solutions like those at issue here were routinely sold at discounts up to 99% below AWP (a 10,000% spread).
- Barron's Magazine published an investigative story in 1996, detailing the precise scheme that Ven-A-Care would later incorporate into its amended complaint – explaining how pharmaceutical companies "market the spread" and even identifying Abbott by name as allegedly maintaining inflated AWPs for vancomycin and solutions.

In light of these references, and the others recounted in Abbott's opening motion, there can be no doubt that Ven-A-Care's complaints are based upon information that was publicly disclosed. Ven-A-Care's action can only stand, therefore, if it can demonstrate that it was the original source of the public disclosures. This Ven-A-Care cannot do. By its express terms, the FCA does not recognize a corporation as an original source. And even if that were not the case,

Ven-A-Care would still fall far short of the mark because its allegations were based not on "direct and independent knowledge," as required by the FCA, but rather on collateral research of GPO price lists and other materials that were widely available. Whatever its contributions in other matters, Ven-A-Care is simply not a proper *qui tam* relator in this case, and this Court has no subject matter jurisdiction to entertain Ven-A-Care's claims. They must be dismissed.

I. THE ALLEGATIONS OF THE FIRST AMENDED COMPLAINT ARE BASED UPON PUBLIC DISCLOSURES

Ven-A-Care bristles at Abbott's invitation for the Court to consider original source issues before turning to public disclosures. (VAC Br. at 33.) No matter; even taken in Ven-A-Care's preferred order, the facts still lead inexorably to Ven-A-Care's dismissal.

A. The Alleged Inflation Of AWPs For The Subject Drugs Was Publicly Disclosed Before Ven-A-Care Brought Its Complaint.

1. In 1992, OIG Disclosed "Mega-Spreads" On Vancomycin.

In its original 1995 complaint, Ven-A-Care alleged that the compendia-published AWPs for vancomycin were substantially higher than the actual average market prices for the drug. The same allegations were published by the Government itself three years earlier.

In 1991, HCFA (now CMS, the federal agency that administers the Medicare and Medicaid programs), asked OIG to investigate the relationship of AWP to actual acquisition cost for drugs used in conjunction with dialysis treatments. OIG focused its study on vancomycin and two other drugs. As part of its investigation, OIG collected actual invoices from providers across the country, including invoices for Abbott's vancomycin. OIG then compared the invoice prices to the published AWPs, the same thing Ven-A-Care did a few years later. In 1992, OIG published the results of its investigation – broadcasting to the world its finding that the median AWP of a 500 mL vial of vancomycin was $19.17, while the actual average cost was only $5.00

(a spread of 283%). (Ex. L.)[1] Viewed through the lens of the accepted *Springfield Terminal* test, this OIG report included both the X (the allegedly false AWP) and the Y (the true price) and thus constitutes a disqualifying public disclosure. *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994).

Tellingly, Ven-A-Care says nothing about this OIG report in its 49-page response. Instead, it seeks to sweep away this and all other OIG reports cited by Defendants as irrelevant in light of this Court's decision in *United States ex rel. Ven-A-Care v. Actavis Mid-Atlantic, LLC*, 2009 U.S. Dist. LEXIS 92945 (D. Mass. Oct. 2, 2009). OIG's 1992 vancomycin report is a far cry from the report this Court found wanting in *Actavis*, however. In that decision, the Court rejected an OIG report as a public disclosure where it merely discussed "average prices" in "generalized industry-wide terms." *Actavis*, 2009 U.S. Dist. LEXIS 92945 at *10-11, 14-15. Here, in stark contrast, OIG's 1992 report identifies a specific drug (vancomycin) and documents an average 283% spread (or "mega-spread," as Plaintiffs characterize it) between the market price and the amount Medicare would pay.

Nor can OIG's report be brushed aside, as DOJ suggests (Gov. Br. at 8), merely because it does not use the word "fraud" or mention Abbott by name. The *Springfield Terminal* test is disjunctive – a public disclosure bars a relator's claims if it reveals *either* X (allegedly false facts) + Y (true facts) *or* Z (the allegation of fraud). *Springfield Terminal*, 14 F.3d at 654. The whole point of *Springfield Terminal* is that "fraud" (Z) need not be mentioned by name in order for a public disclosure of X and Y to trigger the bar. *See United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 919 (D.C. Cir. 1999) (relator is barred where there has been a public disclosure of a fraudulent transaction, even without the specific allegation of fraud).

[1] Unless otherwise noted, exhibit cites used herein refer to exhibits that were appended to Abbott's original motion (Dkt. No. 6179.)

Because OIG's 1992 vancomycin report plainly discloses both X and Y, no more is required. Similarly, the law is clear that a public disclosure need not mention an alleged wrongdoer by name. It is enough if it "'set[s] the government squarely on the trail of fraud,' such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 383 n. 10 (D. Mass. 2008). For instance, in *In re Natural Gas Royalties Qui Tam*, 562 F.3d 1032 (10th Cir. 2009), the relator sued 220 defendants in the natural gas industry, alleging misconduct relating to the calculation of royalties due to the government. Prior to the relator's complaint, however, Senate documents were published that described similar misconduct within this industry. Despite the fact that the Senate documents did not identify all alleged bad actors by name, the Tenth Circuit found that they were sufficient to put the government on the trail of the fraud and to allow the government to "target its investigation toward specific actors and a specific type of fraudulent activity." *Id.* at 1042. Thus, the documents constituted an invalidating public disclosure, undermining relator's case.

The Tenth Circuit's rationale is even more applicable here. When OIG published its report in 1992, only *four* companies manufactured vancomycin, including Abbott. (*See* Ex. M.) There can be no doubt that an OIG report detailing the alleged inflation of AWP for vancomycin was more than sufficient to put the government "on the trail" of this alleged fraud and to target this tiny group of four companies.[2] (This is especially true when one considers the fact that OIG collected Abbott invoices for vancomycin showing spreads of up to 400% between the AWP and the providers actual cost (*see* Dkt. No. 6448 ¶ 83).) The 1992 OIG vancomycin report thus

[2] Again, this is quite distinct from the OIG papers this Court considered in *Actavis*, where the "Defendants and the drugs at issue [were] not readily identifiable from the generalized discussions of averages in the reports." *Actavis*, 2009 U.S. Dist. LEXIS 92945 at *10-11. The 1992 OIG report at issue here specifically discusses AWP inflation for vancomycin, and there were only four potential culprits.

constitutes a public disclosure.[3] *See also United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (finding industry-wide disclosures sufficient for a "narrow class of suspected wrongdoers - local electrical contractors who worked on federally funded projects over a 4-year period"); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 687 (D.C. Cir. 1997) (finding industry-wide disclosures sufficient because "[l]ittle similarity exists between combing through the myriad of transactions performed by the various defense contractors in search of fraud and finding easily identifiable federal employee organizations that provide vending services on federal property").

2. "Mega-Spreads" On Solutions Were Publicly Disclosed In The 1980's.

Similarly, public disclosures were more than sufficient to put the government "on the trail" of alleged AWP inflation of the solutions at issue in this case long before Ven-A-Care filed its complaint. Indeed, the government *actually was* on the trail of fraud. In 1994, CMS publicly announced the investigation in which it collected invoices for all of Abbott's solutions. (Ex. P.) As important, Bruce Vladeck, then the Administrator of CMS, already knew from articles in *Modern Healthcare* magazine that products such as the Abbott solutions were routinely sold at discounts up to 99% off of AWP (spreads up to 10,000%). (Abt. Br. at 16-17.) As Abbott pointed out in its opening papers, at least one of these *Modern Healthcare* articles mentioned Abbott by name and announced that Abbott's "IV solutions" were sold in the marketplace at "an 80% discount off current list prices." (*Id.*)

[3] Even Ven-A-Care does not contest that the "based upon" element of the public disclosure bar would be met by the 1992 OIG report. A relator's allegations are "based upon" a public disclosure when they are "similar to, supported by, or the same as those that have been publicly disclosed regardless of where the relator obtained his information." *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 377-79 (D. Mass. 2008). Ven-A-Care's allegations regarding the alleged AWP inflation of vancomycin closely mirror the findings in OIG's 1992 report.

Ven-A-Care argues that this publication pre-dated Ven-A-Care's complaint by 15 years and focused on discounts available to hospital customers. (VAC Br. at 36-37.) So? The fact that mega-spreads for solutions, including Abbott's solutions, were well known and broadcast in 1980 only makes it *more* clear that Ven-A-Care's 1995 complaint on the subject was old news. And, since hospitals were far and away the largest customer base for Abbott's former Hospital Products Division (accounting for 90% of revenues),[4] an article announcing that hospital customers paid 80% off of list price for Abbott's solutions was very relevant to inform the public and the government that list prices were substantially higher than actual market prices – something Ven-A-Care would call fraud 15 years later. However much Ven-A-Care would like to diminish their importance, the *Modern Healthcare* articles were more than sufficient to put the government "on the trail" of the alleged AWP inflation of Abbott's solutions. Indeed, Administrator Vladeck and CMS's 1994 investigation into AWP inflation confirm that such public knowledge was not just capable of putting the government on the trail, but actually did so.

B. The Alleged "Marketing The Spread" Activity Was Publicly Disclosed Before Ven-A-Care Added Such Claims To Its Complaint.

As noted in Abbott's opening brief, allegations about certain pharmaceutical companies "marketing the spread" were broadcast in media articles in 1987 and 1996, but did not appear in Ven-A-Care's complaint until 1997. (Abt. Br. at 12-14.) Ven-A-Care's various attempts to escape the import of these public disclosures all fail.

1. 1996 Barron's Article

Ven-A-Care admits that the 1996 Barron's article (Ex. J) is a public disclosure of its allegations against Abbott relating to the Subject Drugs and marketing the spread, but suggests that "it is not a disabling public disclosure, however, because it was published approximately one

[4] *See* Dkt. No. 6448 ¶ 7.

year *after* VAC filed its action against Abbott naming these drug products." (VAC Br. at 22.) Ven-A-Care misses the point. Although it is true that Ven-A-Care first lodged a complaint about these products in 1995, the public disclosure inquiry focuses on when Ven-A-Care first made allegations relating to marketing the spread. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473-74 (2007) (courts "look to the amended complaint to determine jurisdiction" to avoid a "relator . . . plead[ing] a trivial theory of fraud" and "later amend[ing] the complaint to include theories copied from the public domain or from materials in the Government's possession.") That did not happen until Ven-A-Care filed an amended complaint on August 12, 1997 – about a year after the Barron's article.

To avoid disqualification, Ven-A-Care now claims that its original 1995 complaint included allegations that Abbott marketed the spread, but the only support it offers is a single paragraph generally claiming that the mere existence of high AWPs acted as an inducement to providers to buy Abbott's products. (VAC Br. at 35.) Nothing in that paragraph suggests in any way that Abbott was actively marketing the spread on the Subject Drugs. After the Barron's article was published, however, Ven-A-Care amended its complaint, alleging that Abbott representatives actively market the spread to customers as a reason to buy Abbott's products. (Ex. B ¶ 48.) In so doing, Ven-A-Care was simply incorporating into its complaint the same "scheme" Barron's had broadcast a year earlier – precisely what the public disclosure bar forbids. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007).

2. 1987 Lexington Herald-Leader Article

Years before Barron's ran its story, a Kentucky newspaper ran a front page exposè devoted entirely to the subject of pharmaceutical companies inflating AWPs and "playing the spread" to drive product sales. (Ex. K.) Ven-A-Care grudgingly concedes that this article

"constituted some disclosure of possible fraud similar to that later alleged by VAC," but then tries unconvincingly to avoid the consequences of that fact. (VAC Br. at 20-21.)

First, Ven-A-Care shrugs off the article as "little noticed" and arising from a "small media market." Ven-A-Care offers no facts whatsoever regarding who "noticed" this article, nor does it offer a single case or statute suggesting how actual reader "notice" would matter to the application of the public disclosure bar, which is based upon publication. And to the extent that it does matter, the fact is that the government itself "noticed" the *Lexington* article and cited it in a 1989 OIG report. (Ex. U at 5.) Similarly, Ven-A-Care offers no support for a "small media market" exception to the public disclosure bar. These attempted evasions are frivolous.

Second, Ven-A-Care makes several of the same bad arguments it raised in conjunction with the OIG reports – that the *Lexington* article does not mention Abbott by name and does not specifically call the conduct at issue "fraud." (VAC Br. at 21.) As discussed above in Part I.A.1, however, none of that is required for a public disclosure. It is enough that the article could put the government "on the trail" of the alleged fraud and those responsible. *Natural Gas*, 562 F.3d at 1042; *In re Pharm. Indus. AWP Litig.*, 538 F. Supp 2d at 383 n. 10. A front page article addressing AWP inflation and marketing the spread – which even Ven-A-Care admits "foretold possible additional fraud in the future" (VAC Br. at 21) – would certainly seem to suffice.

Finally, Ven-A-Care notes that the federal government implemented certain changes in 1987 to the Medicaid regulations concerning drug pricing. (*Id*.) What these unspecified changes have to do with the *Lexington* article is not clear and Ven-A-Care does not explain. Regardless of what changes may have been made to regulations, the fact remains that the *Lexington* article broadcast in 1987 the very "scheme" that Ven-A-Care would weave into its complaint about a decade later. The public disclosure bar precludes relator status in just such situations.

II. VEN-A-CARE IS NOT AN ORIGINAL SOURCE OF THE ALLEGATIONS IN THE FIRST AMENDED COMPLAINT

Because Ven-A-Care's allegations against Abbott were based upon public disclosures, the Court lacks subject matter jurisdiction unless Ven-A-Care can establish that it was the original source of the disclosures. *See* 31 U.S.C. § 3730(e)(4)(A). Ven-A-Care cannot do so.

A. As A Corporation, Ven-A-Care Cannot Be An Original Source.

The FCA provides that "persons" can bring cases under the Act and share in the recovery, but only "an *individual* who has direct and independent knowledge" can be deemed an original source. (Abt. Br. at 4-5; *see also* 31 U.S.C. § 3730(e)(4)(B).) As the First Circuit held when faced with a similar question of statutory interpretation, "person" includes corporations, but "individual" does not. *See In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003). Thus, by the plain terms of the FCA, Ven-A-Care cannot qualify as an original source.

In response, Ven-A-Care points to several cases where corporations have in fact participated in FCA actions, but not a single one of these decisions actually considers the challenge raised here by Abbott – namely, whether the statutory text of the FCA precludes corporations from being an original source. The closest is *In Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1048-50 (8th Cir. 2002), in which the court found that a Minnesota unincorporated association could be a proper relator. That decision, however, was based on the theory that, under state law, the association had no legal status separate from its members and therefore had standing to bring suit on behalf of its individual member's rights. *Id.* at 1050 (drawing a contrast with "a corporation [that] has no standing to assert rights belonging to its shareholders"). The Eighth Circuit did not perform any statutory analysis of the FCA, or discuss the legal presumption that different words in the same statute have different meanings. (*See* Abt. Br. at 5-6 (collecting cases).) This Court will,

therefore, be writing on a clean slate with respect to this issue. Ven-A-Care has offered no support, statutory or otherwise, that would permit this Court to redraft the FCA to eliminate the "individual" requirement from the original source provision. The Court should decline Ven-A-Care's invitation to engage in such judicial draftsmanship, and instead should find that, as a corporation, Ven-A-Care is not an "individual" and therefore not an original source.

B. Even Absent The Statutory Disqualification, Ven-A-Care Is Not An Original Source.

Even if Ven-A-Care could overcome the statutory hurdle (and it cannot), it still does not qualify as an original source as a matter of law. There is no dispute that, in order to be an original source, the relator must have "both 'direct' and 'independent' knowledge" of the information upon which each of his or her claims is based. *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d at 379; *Rockwell*, 549 U.S. at 470-71. For knowledge to be "direct," it must be "firsthand," *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 690 (D.C. Cir. 1997), and for it to be "independent," the knowledge must be separate from any public disclosures and "must not be derivative of the information of others," *United States ex rel. Fine v. Advanced Scis., Inc.*, 99 F.3d 1000, 1007 (10th Cir. 1996). Ven-A-Care fails on all counts.

Ven-A-Care does not and cannot claim to have *any* direct or independent knowledge supporting the allegations first made in its 1997 amended complaint concerning Abbott's supposed efforts to market the spread on the Subject Drugs. Ven-A-Care's witnesses conceded as much at their depositions (*see* Abt. Br. at 8-9), and that should end this discussion. Ven-A-Care is not an original source as to any allegation that Abbott marketed the spread.

Ven-A-Care at least tries to claim direct and independent knowledge of its allegations concerning AWP inflation for the Subject Drugs, but it again falls short. Ven-A-Care has made clear all along that these allegations are based not on some direct knowledge, but rather on

collateral research and compilation of information from secondary materials that were available to many others, such as the publishing compendia and GPO price catalogs. (Abt. Br. at 9-10.) Ven-A-Care argues that this sort of research effort is sufficient (VAC Br. at 28-29), but the law says otherwise. In this Court's own words, "any information supporting a FCA action that Relator gained through his analysis of existing data is [ ] insufficiently direct to make him an original source." *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 96 (D. Mass. 2001); *see also United States ex rel. Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) ("collateral research and investigations . . . [do] not establish 'direct and independent knowledge of the information on which the allegations are based within the meaning of § 3730(e)(4)(B)'"); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463-64 (S.D.N.Y.) ("the 'perspective' [of relator's] members obtained by spending hundreds of hours compiling facts into a 'mosaic,'" was not sufficient to satisfy the original source requirement), *aff'd*, 53 F. Appx. 153 (2d Cir. 2002).[5] This sort of secondary research is all Ven-A-Care can offer, and it is not enough.

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Because Ven-A-Care's allegations against Abbott are based upon public disclosures for which Ven-A-Care is not the original source, its complaint must be dismissed.

[5] This case is quite different from the *Kennard* and *Ervin* matters cited by Ven-A-Care (VAC Br. at 28-29). In *Kennard*, the court specifically noted that the misconduct alleged was not disclosed in any public documents and that relators "were not just assemblers of information." 363 F.3d at 1046. Similarly, the relator in *Ervin* conducted an independent investigation, filing numerous FOIA requests and interviewing witnesses, and ultimately brought forward to the government core allegations of the fraud that were not previously disclosed. 332 F. Supp. 2d at 9. In stark contrast, the allegations Ven-A-Care makes against Abbott *were* publicly disclosed, and Ven-A-Care admits that its complaint is based on no more than review of the compendia, GPO price lists, and other widely available information.

III. THE UNITED STATES' COMPLAINT-IN-INTERVENTION CAN CONTINUE, BUT IT CANNOT RELATE BACK TO VEN-A-CARE'S 1995 COMPLAINT

In its separate response, the Government argues that, even if Ven-A-Care is dismissed, the Government's 2006 complaint-in-intervention should still relate back to Ven-A-Care's 1995 complaint. (Gov. Br. at 2-6.) That is wrong as a matter of law. "[I]t is axiomatic that in order for the doctrine of relation back to apply, the prior pleadings must be properly filed and the court must have jurisdiction over the claim at the time of the prior pleadings." *Austin v. Trandell*, 207 F. Supp. 2d 616, 624-25 (E.D. Mich. 2002) (citing cases). Accordingly, Rule 15's "relation back doctrine only operates to give a plaintiff the benefit of an earlier filing date if the court in which the matter was first filed had jurisdiction over the matter at that earlier date." *Salazer v. United States Postal Serv.*, 929 F. Supp. 966, 970 (E.D. Va. 1996) (citing cases).[6] This Court's apt statement in another matter – "[i]f the Court did not have jurisdiction over Ven-A-Care's" pleadings, "the government's complaint-in-intervention cannot properly relate back" – is entirely consistent with this settled law. *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 399-400 (D. Mass. 2007).[7]

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[6] *See also USM Corp. v. GKN Fasteners Ltd.*, 578 F.2d 21, 23 (1st Cir. 1978); *Holloway v. United States*, 60 Fed. Cl. 254, 261, 265 (2004) (holding "present complaint does not and cannot 'relate back'" to initial complaint, as "court was at that time without jurisdiction"); *Brewer-Giorgio v. Producers Video, Inc.*, 216 F.3d 1281, 1285 (11th Cir. 2000) (plaintiff's untimely claims in copyright action did not relate back to original complaint for which court lacked subject-matter jurisdiction); *Kreider Dairy Farms, Inc. v. Glickman*, 190 F.3d 113, 121 (3d Cir. 1999); *Reynolds v. United States*, 748 F.2d 291, 293 (5th Cir. 1984); *Morgan v. Hanna Holdings, Inc.*, 635 F. Supp. 2d 404, 410-11 (W.D. Pa. 2009) ("an amendment cannot relate back to a complaint over which the Court did not have subject matter jurisdiction"); *Wellness Publishing v. Barefoot*, Civ. A. No. 02-3773 (JAP), 2008 WL 108889, *10 (D.N.J. Jan. 9, 2008) (same); *In re Eldridge*, 348 B.R. 834, 846 (N.D. Ala. 2006) ("The filing of an complaint, such as the one here, by someone without standing is considered a *nullity* and it will not support the relation back of an amendment to the same substituting or adding as plaintiff one who has standing in the event the applicable statute or limitations.").

[7] The Government itself has recognized this well-established principle. *See, e.g., Penn Millers Ins. Co. v. United States*, 472 F. Supp. 2d 705, 709 (E.D.N.C. 2007) (accepting "the government conten[tion] that this court lacked subject matter jurisdiction . . . over [plaintiff's] complaint and thereby

The Government's counter-arguments are meritless. The Government first claims that relation back is supported by the result in *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007). But "[p]rior cases have precedential value only when there has been a deliberative consideration of the issue at hand." *Bannon v. Edgewater Med. Ctr.*, 406 F. Supp. 2d 907, 927 (2005). Neither the Supreme Court, Tenth Circuit, nor the district court in *Rockwell* ever considered the relation-back issue posed here; the issue was never raised by the parties. (*See* Gov. Br. at 4 (admitting the "Supreme Court did not address the statute of limitations directly").)

In fact, *Rockwell* explicitly rejected the linchpin of the Government's argument here. Without citing a shred of authority, the Government contends that "the relator's original complaint is *now treated as if filed by the United States*, with the United States' complaint-in-intervention relating back to the original complaint." (Gov. Br. at 4) (emphasis added). But *Rockwell* could not have been clearer in rejecting this very argument:

> The statute draws a sharp distinction between actions brought by the Attorney General under § 3730(a) and actions brought by a private person under § 3730(b). An action brought by a private person *does not become one brought by the Government* just because the Government intervenes and elects to 'proceed with the action.'

549 U.S. at 477 (emphasis added). *Rockwell* then held that the district court did not have jurisdiction over the United States' claim until the relator was dismissed from the action, such that the claim was now a *separate action* brought by the Attorney General. *Id.* at 478.

This part of *Rockwell*'s holding is consistent with the "longstanding and clear rule is that 'if jurisdiction is lacking at the commencement of [a] suit, it cannot be aided by the intervention

(continued…)

lacked the power to permit the complaint to be amended or to permit the amended complaint with the substituted plaintiff to relate back to the original complaint").

of a [plaintiff] with a sufficient claim.'" *Pressroom Unions-Printers League Income Sec. Fund. v. Cont'l Assur., Co.*, 700 F.2d 889, 893 (2d Cir. 1983). As the Government conceded in *Rockwell* (*see* 549 U.S. at 477 n. 7), even in FCA actions an intervention by the Government cannot cure any pre-existing jurisdictional defects in the relator's pleadings.[8] Because Ven-A-Care's complaint "does not become one brought by the Government just because the Government intervenes," *Rockwell*, 549 U.S. at 477, it must be evaluated independently; if, as here, the Court had no subject matter jurisdiction over the original Ven-A-Care complaint, then there is no way for the Government's later complaint-in-intervention to relate back.

For this reason, the Government's reliance on *Connectu v. Zuckerberg*, 522 F.3d 82 (1st Cir. 2008), is misplaced. In *Connectu*, the plaintiff filed an amended complaint that switched the district court's subject-matter jurisdiction from diversity to federal question. The court based its decision on the fact that plaintiff's amended complaint did not seek to "cure" a jurisdictional defect by "engaging the gears of Rule 15(c)'s relation back mechanism." *Id.* at 94. Rather, the plaintiff in *Connectu was* capable of establishing jurisdiction simply by invoking a federal question, rather than diversity jurisdiction. *Id.* at 94-95. The district court in *Connectu* thus *did* have subject matter jurisdiction over plaintiff's original complaint.

Here, by contrast, the Government is trying to use the relation back of its complaint-in-intervention to *create* subject-matter jurisdiction over Ven-A-Care's 1995 complaint that in fact did not – even latently – exist. This is not permissible. As has been held in analogous situations where the court did not have jurisdiction over the original complaint, the Government's intervention is properly treated as a *separate action* which does not relate back. *See Pressroom*,

[8] *See also USM Corp.*, 578 F.2d at 23; *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 452-53 (5th Cir. 1995) (when relators' FCA claims are subject to dismissal under the public disclosure bar, the government may still intervene that intervention does not cure the defect in relators' claims).

700 F.2d at 893 (affirming denial of plaintiff's motion to amend complaint to substitute new plaintiffs necessary to confer subject-matter jurisdiction, noting amendment would not have "relate[d] back to original suit" but instead "would be a new action") (internal citations omitted); *United States Steel Corp. v. EPA*, 614 F.2d 843, 845046 (3d Cir. 1979) (district court was permitted to "treat the pleading of an intervenor as a *separate action*," but "intervention cannot treat a jurisdictional defect"); *Fuller v. Volk*, 351 F.2d 323, 328-29 (3d Cir. 1965) (intervention treated as a "separate action" and cannot "breath life into a 'nonexistent' lawsuit"); *In re Eldridge*, 348 B.R. at 846; *PE Corp. v. Affymetrix, Inc.*, No. Civ. A. 00-629-SLR, 2001 WL 1180280, *2-4 (D. Del. Sept. 27, 2001) (where original plaintiff did not have standing, amendment adding plaintiff with standing "does not relate back" to original complaint); *cf. Holloway*, 60 Fed. Cl. at 261, 265; *Brewer-Giorgio*, 216 F.3d at 1285; *Kreider Dairy Farms*, 190 F.3d at 121; *Reynolds*, 748 F.2d at 293; *Morgan*, 635 F. Supp. 2d at 410-11; *Wellness Publishing*, 2008 WL 108889 at *10; *Austin*, 207 F. Supp. 2d at 624-25; *Salazer*, 929 F. Supp. at 970. As noted in *U.S. ex. rel. Krahel v. Regents of Univ. of Cal.*, the law does not permit a relator's complaint that is jurisdictionally defective to "act as a sort of placeholder until the government decides whether or not to intervene." Nos. C-96-1703, C-01-1893, 2001 WL 1548786, *3-4 (N.D. Cal. Sept. 13, 2001).

Finally, the FERA provision cited by the Government has no application here. That provision does not contemplate relation back to a complaint that could not satisfy the jurisdictional requirements of 3730(e)(4) in the first place. It does nothing to overturn the well-established principle that the "relation back doctrine only operates to give a plaintiff the benefit of an earlier filing date if the court in which the matter was first filed had jurisdiction over the matter at that earlier date." *Salazer*, 929 F. Supp. at 970. Moreover, the FERA provision applies

only to "cases pending on the date of enactment," a requirement not met here. An action is not "pending" unless the person who filed the action meets all of the jurisdictional requirements of § 3730(e)(4). *See Campbell v. Redding Medical Center*, 421 F.3d 817, 823-24 (9th Cir. 2005). Even today, because Ven-A-Care's inclusion in the case continues to spoil the Court's jurisdiction, this case is not "pending" within the meaning of the FERA relation-back provision.

Furthermore, *Rockwell* made clear that the FCA's public disclosure bar (§ 3730(e)(4)) covers not only the court's power, but also the "substantive rights of the parties." 549 U.S. at 468. Permitting the Government's claims to relate back to Ven-A-Care's 1995 complaint would retroactively create jurisdiction where none existed, and would impermissibly expose Abbott to liability for claims that are time-barred under the FCA's six-year statute of limitations. *See U.S. v. Aguillon*, 628 F. Supp. 2d 542 (D. Del. 2009) (holding that relation back under FERA § 4(f)(1) would cause impermissible "retroactive effects").

CONCLUSION

For all of the reasons discussed above and in Abbott's original motion, Ven-A-Care's complaint against Abbott should be dismissed for lack of subject matter jurisdiction. In addition, although the Government's March 2006 complaint-in-intervention against Abbott can continue despite the dismissal of the relator, it should not be allowed to relate back to Ven-A-Care's earlier, jurisdictionally-defective complaints.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION UNDER THE PUBLIC DISCLOSURE BAR to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 23d day of November, 2009.

/s/ Brian J. Murray
Brian J. Murray